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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,930	11/09/2001	Achim Harder	Mo-6752/LeA 33,583	5556

7590 05/19/2004

BAYER PHARMACEUTICALS CORP  
400 MORGAN LAND  
WEST HAVEN, CT 06516-4175

EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,930	HARDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 February 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 7-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment filed February 10, 2004 is acknowledged and has been entered. Claims 3-6 have been canceled. Claims 2 and 7-10 have been amended. Claims 1, 2 and 7-10 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, Applicants have not filed an English translation of these priority documents (PCT/EP00/04014 and Germany 19921887.0). The effective filing date of the present application is November 9, 2001.

Applicant cannot rely upon the foreign priority papers to overcome any prior art rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.
4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9, as presently amended, is vague and indefinite in that it does not depend from any claim 9, but recites a wherein

clause as if it does depend from a claim. Claim 9 states “The method of wherein piperazines...”; as presently written, the claim does not makes sense.

5. Claims 1, 2, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by von Samson-Himmelstjerna et al (European J. Neuroscience, 2000, 12/Suppl.11:43).

The claims are directed to an endoparasiticidal composition comprising piperazines together with cyclic depsipeptides consisting of amino acids and hydroxycarboxylic acids as ring units and having 24 ring atoms, and a method for increasing the endoparasiticidal action of cyclic depsipeptides comprising contacting the endoparasites with the composition.

von Samson-Himmelstjerna et al discloses cyclic depsipeptides (PF 1022A and Bay 44-4400) and that these compounds stimulate the GABAergic neurotransmission and simultaneously inhibits the cholinergic system. The prior art discloses the effects of Bay 44-4400 in the presence of the well-known GABA agonist piperazine against different mouse nematodes. A synergistic effect between Bay 44-4400 and piperazine was observed due to an increased anthelminic in vitro activity against *T. spiralis* larvae, to an accelerated worm expolusion of *H. polygyrus* or *H. spumosa* from the intestines of infected mice and to a significantly higher degree of degenerating effects of the intestine and on the nerve cord of *H. spumosa* compared to the effects of the single compounds (see abstract).

The prior art discloses the claimed invention. The compositions of the prior appear to be the same or an obvious or analogous variant. The methods appear to have the same result as claimed by Applicants. Since the Patent Office does not

have the facilities for examining and comparing applicants' composition and method with the composition and method of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and method and the composition and method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 1, 2 and 7-10 under 35 U.S.C. § 102(b) as anticipated by von Samson-Himmelstjerna et al is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1, 2 and 7-10 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed February 10, 2004, have been fully considered but they are not deemed to be persuasive.

Applicants have asserted that the enclosed is a certified translation of the German priority document, DE 199 21 877.0 and that this certified translation allows applicants to claim the priority date of May 12, 1999. Applicants have asserted that the priority date of May 12, 1999 establishes that the article cited by the Examiner, von-Samson-Himmelstjerna et al, does not qualify as prior art under 35 U.S.C. 102 (b), and that the rejection based on this document should be withdrawn.

However, a certified translation of the German priority document, DE 199 21 877.0 was not filed with the amendment of February 10, 2004. The effective filing date of the current application is November 9, 2001 and as such the 102 (b) prior art rejection is maintained.

6. Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Nicolay et al (Parasitol. Res., 2000, 86:982-992).

Nicolay et al discloses a study of the synergistic effects on cyclic depsipeptide and piperazine in the treatment against nematodes (abstract, p. 982; figures 2-4). Nicolay et al discloses that an additive effect was observed, piperazine alone exerted an efficacy of 54.4% and cyclic depsipeptide alone exerted an efficacy of 44.4%, whereas the combination of these compounds had an efficacy of 97.5% (abstract; materials and methods, figures 2-4, table 1).

The prior art discloses the claimed invention. The compositions of the prior appear to be the same or an obvious or analogous variant. The methods appear to have the same result as claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' composition and method with the composition and method of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and method and the composition and method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 1, 2 and 7-10 under 35 U.S.C. § 102(a or b) as anticipated by Nicolay et al is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1, 2 and 7-10 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed February 10, 2004, have been fully considered but they are not deemed to be persuasive.

Applicants have asserted that the enclosed is a certified translation of the German priority document, DE 199 21 877.0 and that this certified translation allows applicants to claim the priority date of May 12, 1999. Applicants have asserted that the priority date of May 12, 1999 establishes that the article cited by the Examiner, Nicolay et al, does not qualify as prior art under 35 U.S.C. 102 (a or b), and that the rejection based on this document should be withdrawn.

However, a certified translation of the German priority document, DE 199 21 877.0 was not filed with the amendment of February 10, 2004. The effective filing date of the current application is November 9, 2001 and as such the 102 (a or b) prior art rejection is maintained.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

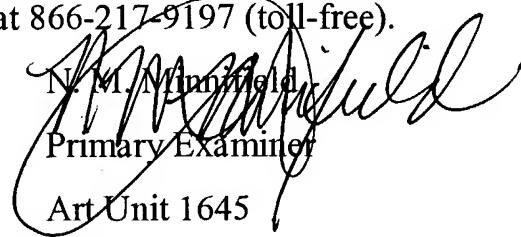
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield  
Primary Examiner  
Art Unit 1645

NMM

May 14, 2004